EBOLA FREQUENTLY ASKED QUESTIONS (FAQ) AND ANSWERS

Updated 3/23/15 (see red text for most current updates)

A. TESTING DETAILS

1. Does Virginia's public health laboratory conduct Ebola testing?

Yes. The Division of Consolidated Laboratory Services, within the Virginia Department of General Services, is one of **63** LRN laboratories nationwide that is qualified and approved by the Centers for Disease Control and Prevention to perform the Department of Defense (DOD) Emergency Use Authorization (EUA) Ebola Zaire (EZ1) rRT-PCR TaqMan® assay. DCLS is the only laboratory in Virginia that has this testing capability.

2. How does this Ebola test work?

PCR, or Polymerase Chain Reaction, is a molecular analysis technique in which the genetic material of the Ebola virus is amplified or replicated to produce thousands to millions of copies. These amplified copies can be detected by using Ebola -specific probes that target specific sequences within the Ebola virus genome, which is detected using specific instrumentation in the laboratory. If Ebola specific amplification is detected in a patient's specimen, then that specimen is considered to be presumptively positive for Ebola virus.

3. Does the DOD EUA Ebola PCR assay detect all strains of the Ebola virus?

No. The DOD EUA Ebola PCR assay detects the presence of the Ebola virus Zaire strain only. The Zaire strain is the agent implicated in the current West Africa Ebola outbreak.

4. How many suspect Ebola cases have been tested at DCLS?

DCLS has performed Ebola virus testing on six suspect cases. All six cases yielded negative results.

5. Will DCLS perform testing for other diseases while testing for the Ebola virus?

DCLS can perform Malaria testing for suspect Ebola cases, as the symptoms for Malaria are very similar to symptoms presented by persons infected with the Ebola virus. Malaria testing is performed on all specimens that test negative for Ebola virus. Additionally, DCLS has the capability to perform rapid molecular testing for Norovirus, Rotavirus and Influenza, and enteric bacterial culture testing as warranted by patient symptomology.

6. Does DCLS perform only Ebola testing on these patients or do they also perform routine labs?

DCLS will perform Ebola virus testing only IF approved by VDH and CDC. If Ebola virus test results are negative, DCLS will follow up with Malaria testing using a real-time PCR assay.

The Malaria real-time PCR assay will detect the presence of DNA for *Plasmodium falciparum*, *Plasmodium ovale*, *Plasmodium malariae* and *Plasmodium vivax*.

7. What is the turnaround time for Malaria, and other non-Ebola test results?

Other rapid molecular test results can be provided within 4-5 hours after testing has been initiated. The decision to perform additional testing outside of normal business hours will be assessed on a case by case basis.

Negative enteric bacterial culture results may be provided within 48-72 hours. Reporting of presumptive positive enteric culture results will take longer, as confirmatory testing will be required.

8. Our facility has instituted a Trizol protocol to inactivate Ebola virus. Should we send a Trizol-inactivated blood specimen to DCLS for Ebola virus testing?

No, DCLS will only accept non-inactivated whole blood specimens collected in two lavender-top blood tubes. Trizol-inactivation may interfere with other analytical testing that may be performed on the specimens.

Specimens forwarded to CDC for confirmatory or additional testing will not be inactivated prior to shipping.

B. CONSULTATION & APPROVAL

1. Who do I call if there's a suspect Ebola virus case at my facility? Who determines if a suspect case warrants testing for Ebola virus?

Contact your local epidemiologist or Virginia Department of Health (VDH) immediately to have the case viewed. VDH, in consultation with the Centers for Disease Control and Prevention, has the responsibility of investigating all suspect cases, determining exposure risk (high, low or none), and requesting testing if clinical symptoms and travel history meet the case definition. Final approval from the CDC is required before testing can be initiated by state laboratories such as DCLS.

2. How do I find out who my local epidemiologist is?

Please use the link below to obtain contact information for your local health department. It is highly recommended that local health department contact information be posted in your laboratory: http://www.vdh.virginia.gov/LHD.

C. SPECIMEN COLLECTION/TRANSPORT/SUBMISSION

1. If a patient presents with mild symptoms and travel history within the first 72 hours of onset, should specimen collection take place at that time, or would it be best to wait until the patient has been ill for at least 72 hours?

If Ebola virus infection is suspected and testing has been approved by VDH and CDC, specimens should be collected as soon as possible and submitted to DCLS for testing.

2. Should specimens be recollected if the initial specimen was collected less than three days post onset and the initial PCR result is negative?

Yes. Another set of specimens should be collected at least three days post onset of symptoms submitted for retesting before considering the negative test to be valid. An exception would be if an alternate diagnosis was made and patient's clinical presentation is improving and other lab testing (i.e., CBC, liver enzymes) are within normal limits. This will be decided on a case-by-case basis with consultation from VDH/DCLS.

3. What specimens are acceptable for testing?

Whole blood is the preferred specimen type for the Ebola Zaire (EZ1) rRT-PCR TaqMan® assay.

A nasopharyngeal (NP) swab in viral transport media (VTM) is the acceptable specimen type for Influenza real-time PCR testing.

Raw stool specimen and/or stool specimen in Cary Blair media are the acceptable specimen types for Norovirus and Rotavirus real-time PCR assays, and Enteric bacterial culture testing.

NOTE: Stool specimens should be collected immediately upon suspicion of a GI pathogen and BEFORE administering antibiotics to the patient.

4. How do hospital laboratories submit specimens to DCLS for Ebola virus testing?

Once a suspect case has been investigated and approved for testing by the Virginia Department of Health and the Centers for Disease Control and Prevention, DCLS will arrange for a special courier pickup. The specimens will be delivered to DCLS immediately.

NEW DEVELOPMENT: **To comply with Department of Transportation (DOT) regulations, all suspect Ebola specimens will have to be packaged as "Risk Group 4" Category A specimens by individuals certified to prepare Category A packages only. Contracted couriers cannot transport Category A packages that have not been prepared by certified individuals. DCLS is working on other alternatives to have suspect Ebola specimens transported to DCLS for testing for those facilities that are not certified to ship Category A packages.**

5. Can DCLS send shipping kits to hospitals?

DCLS has provided approved shipping kits to all health districts and all facilities that currently have Category A certified staff . Please contact DCLS if your facility has Category A certified staff and are in need of approved shipping kits.

6. If our hospital staff has a courier, should we use it to transport specimens to DCLS?

No. DCLS will dispatch a special courier pickup, using a state-contracted, bonder courier to pick up and deliver specimens for testing.

7. Who will facilitate sending additional specimens to CDC for confirmatory testing?

Hospitals are required to submit two purple-top blood tubes to DCLS for testing. One of the tubes will be tested at DCLS. DCLS has the responsibility for forwarding the second blood tube to the CDC.

8. Will the DCLS courier accept a suspect Ebola virus specimen if the Shipper's Declaration Form is handwritten?

Yes, DCLS courier will accept the specimen but handwriting must be legible. In addition, 2 copies of the Shipper's Declaration form must contain the red and white diagonal hatch marks.

9. What is the recommended PPE for preparing a suspect Ebola patient specimen for transport? Should personnel preparing the specimen for transport use the same PPE worn by nursing staff that are caring for patients?

Personnel should follow their facility's policies on PPE requirements for handling Ebola specimens. However, personnel handling Ebola specimens for packaging/transport could be at risk of exposure in the event the specimen tube leaks, breaks, etc. It is recommended that the same PPE used by nursing staff be used by personnel preparing the specimen for transport at least until the specimen is securely contained in the secondary shipping receptacle.

10. Should Ebola specimens packaged in transport containers remain in the patient's room until the courier arrives to transport the specimen to DCLS?

Specimens packaged for transport to DCLS should not remain in the patient room, as the shipping box could potentially be contaminated with patient bodily fluids. Specimens should be packaged in the primary and secondary shipping receptacles while in the patient's room and the secondary receptacle containing the specimen should be disinfected prior to exiting the patient's room. The specimen should then be moved to a "clean" area outside of the patient's room for packaging in the tertiary shipping receptacle or shipping box. The shipping box should remain in the "clean" for pick-up by the courier.

D. TEST RESULTS

1. How are the results for the DOD EUA Ebola PCR assay interpreted? What follow-up actions are needed?

The DOD EUA Ebola PCR assay detects the presence of RNA for the Ebola Zaire virus. **Negative test results** are considered **final test results**.

Confirmatory testing of negative results at CDC is NO LONGER required. If fever or symptoms have been present for less than 72 hours, a repeat test may be required to rule out Ebola virus infection.

If Lassa Fever is being considered as a cause of illness, DCLS will refer a blood specimen to CDC for Lassa Fever testing.

All **positive test results** will be confirmed at CDC. DCLS will refer the blood specimen to CDC for confirmatory testing.

2. What is the turn-around time for DCLS PCR results?

The approximate turn-around time for results is 3-5 hours after specimens are received at DCLS. At this time, DCLS is able to perform testing immediately when the specimens arrive at the laboratory but in the event that DCLS begins to receive large numbers of tests requests, DCLS will prioritize testing in consultation with VDH.

3. What is the turn-around time for CDC test results?

Confirmatory tests results from CDC can be received anywhere from a few to several days. CDC is prioritizing testing based on severity of illness and Ebola virus exposure risk level.

E. BIOSAFETY

1. What safety/work practices are used by DCLS staff during Ebola virus testing?

All Ebola virus testing at DCLS is performed in a Biosafety Level 3 (BSL3) laboratory, using BSL3 safety and work practices.

2. What does Biosafety Level 3 (BSL3) mean?

Biosafety level 3 is a level of biological containment measures appropriate for moderate- to high-risk infectious agents. BSL3 agents pose a risk for respiratory transmission via exposure to infectious aerosols, autoinoculation and ingestion. Exposure to these agents may result in serious or lethal infection. Work practices within a BSL3 facility include, but are not limited to, manipulation of infectious agents or specimens inside a biological safety cabinet (BSC), special protective clothing, restricted and controlled access to the laboratory, and special air handling to prevent the release of infectious aerosols outside of the laboratory.

3. What BSL3 safety and work practices will be employed by DCLS staff when performing Ebola virus testing to ensure their protection?

BSL-3 work practices employed at DCLS are consistent with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommendations. This includes wearing the appropriate personal protective equipment (PPE) – fluid resistant gowns, shoe covers, safety glasses, respiratory protection, and two sets of examination gloves. All potentially infectious work is performed inside of a biological safety cabinet (BSC) and all items removed from the BSC are appropriately disinfected prior to removal. All potentially infectious waste generated during Ebola virus testing is decontaminated by autoclaving prior to removal from the BSL3 laboratory.

4. If Ebola virus specimens are analyzed in our laboratory facility, what is the protocol for disinfecting the instruments?

Follow the manufacturer's recommendations for decontamination or visit the CDC website for additional guidance.

5. What is the difference between Risk Group and Biosafety Level classification?

Risk Group: Infectious agents are categorized in four risk groups (risk group 1 - 4) based on their overall risk to cause human or animal disease. Risk group 4 agents pose the highest individual and community risk. The factors considered when designating a risk group classification to an infectious agent include but are not limited to:

- pathogenicity
- mode of transmission
- host types
- availability of effective vaccines
- availability of effective treatment

Biosafety Level: Biosafety level (BSL) classification applies to a combination of laboratory practices and techniques, safety equipment, and laboratory facilities that provide a level of containment adequate to work with infectious agents. There are 4 biosafety level classifications (BSL1 – BSL4), with BSL4 containment applying to dangerous and exotic agents that pose a high risk of life-threatening diseases transmitted via aerosol transmission and for which no vaccine or therapy is available.